

**PATENT**

Attorney Docket No.: 015280-415100US

Client Ref. No.: E-128-2000/0-US-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Samir N. Khleif *et al.*

Application No.: 09/810,310

Filed: March 14, 2001

For: METHODS AND COMPOSITIONS
FOR CO-STIMULATION OF
IMMUNOLOGICAL RESPONSES TO
PEPTIDE ANTIGENS

Customer No.: 45115

Confirmation No. 9099

Examiner: Marianne Dibrino

Technology Center/Art Unit: 1644

DECLARATION OF JAY BERZOFSKY
UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Jay Berzofsky, declare and state as follows:

1. I am a co-inventor of the subject matter of U.S. Patent Application No. 09/810,310, entitled "Methods and Compositions for Co-stimulation of Immunological Responses to Peptide Antigens" (hereinafter "the '310 application" or "the application").

2. I currently hold the position of Chief, Vaccine Branch of the Center for Cancer Research at the National Cancer Institute, National Institutes of Health. I have a Ph.D. in Molecular Biology as well as an M.D. from the Albert Einstein College of Medicine. I have 33 years of post-graduate scientific and biomedical experience, including, for example, in the areas of antigen recognition by T lymphocytes; antigen processing and presentation; vaccine design and development based on immunological principles, peptide synthesis, and recombinant DNA technology; and AIDS, malaria, and cancer vaccines. I have also held editorial positions on several peer review scientific journals, including the Journal of Immunology, Journal of Molecular and Cellular Immunology, Molecular Immunology, Peptide Research, International

SAMIR KLEIF *et al.*
Application No. 09/810,310

PATENT

Immunology, and Clinical Immunology, among others. I have co-authored over 390 scientific papers in the areas of molecular and cellular biology, immunology, and vaccine research. A copy of my curriculum vitae is attached hereto as Exhibit 1.

3. As a co-inventor of the subject matter described in the '310 application, and as a researcher in the fields of immunology and vaccine design (*see* ¶2), I am a person of skill in the art to which the invention as claimed in the application pertains.

4. I have read the Office Action dated April 19, 2006 ("Office Action") issued by Examiner Dibrino.

5. I understand from the Office Action that the pending claims stand rejected as allegedly obvious over U.S. Patent No. 5,942,607 in view of Kaufmann *et al.* (*Cell. Immunol.* 169:246-251, 1996); statements in the specification on page 37, lines 7-18; Rock *et al.* (*Proc. Natl. Acad. Sci. USA* 89:8918-8922, 1992); U.S. Patent No. 5,738,852; WO 98/04705 and the CAPLUS Accession No. 1998:106018 summary thereof; U.S. Patent No. 6,338,947; U.S. Patent No. 6,045,802; and Harlow and Lane (*Antibodies: A Laboratory Manual*, 1988, p. 104).

6. I have read and understand the documents referenced in ¶5 above.

7. I am a co-author of the Shirai *et al.* reference (*J. Immunol.* 152:549-556, 1994), also discussed in the Office Action.

8. The statements set forth herein are offered to address the Examiner's remarks in the Office Action and to show that, as of the filing date of the '310 application, the patent and scientific literature discussed in the Office Action would not have led an artisan of ordinary skill to the invention as presently claimed in the application.

9. Shirai *et al.* describe peptide vaccine studies in which Th and CTL epitopes were administered either as an admixture of non-linked epitopes or as a single peptide with the Th and CTL epitopes covalently linked. The Shirai *et al.* reference shows that any CTL

SAMIR KLEIF *et al.*
Application No. 09/810,310

PATENT

response is very poor if the Th and CTL epitopes are not coupled. (See Figure 2 and corresponding description).

10. With regard to the Examiner's statements that Shirai *et al.* teaches two studies in which covalent linkage of Th and CTL epitopes was not obligatory for inducing a CTL response *in vivo*, I understand the Examiner to be referring to statements in the last paragraph of page 552 of Shirai *et al.* Shirai *et al.* refer to two previous studies in which Th and CTL epitopes were not covalently linked. Shirai *et al.* reconcile these previous studies with their own covalent linkage study. Specifically, Shirai *et al.* note that in one of the previous studies, the Th and CTL determinants were physically together within the same microdroplets of an adjuvant emulsion, and in the other study, the inherent disadvantage of an unlinked mixture was overcome by multiple high doses of peptide. Shirai *et al.* further note that these results are consistent with the requirement for proximity or presentation on the same presenting cell.

11. The skilled artisan reading Shirai *et al.* would understand this reference as teaching that CTL responses are poor if the Th and CTL determinants are either (1) not coupled (e.g., physically in a microdroplet or covalently) or (2) if unlinked, administered at a high dose (for example, at high concentrations) in an admixture.

12. Although the Shirai *et al.* study deals with two peptides rather than a peptide and a DNA molecule, the skilled artisan would understand Shirai *et al.* as demonstrating, *inter alia*, the basic principle that, unless two molecules are linked or administered together at high doses, there is not a reasonable expectation that these agents will be sufficiently accessible to the same cell when administered *in vivo* to effect a corresponding physiological response. In particular, the skilled artisan would not have a reasonable expectation that two molecules (such as two molecules where one is a nucleic acid and the other is a protein or peptide antigen), administered separately to an individual at closely adjacent sites, would be taken up by the same cell. At least to this extent, the skilled artisan would regard Shirai *et al.* as applicable to the consideration of whether separately administered peptide and nucleic acid would be sufficiently accessible to the same antigen presenting cells *in vivo* to effect an immune response.

SAMIR KLEIF *et al.*
Application No. 09/810,310

PATENT

13. With respect to the Examiner's statements regarding the draining of immunogens to the lymph nodes, as noted in the specification, direct injection of DNA into vertebrate tissues had been shown to result in the uptake and expression of the DNA. (See '310 application at p. 37, ll. 11-14.) It was also known as of the application's filing date, however, that DNA typically transfects the cells immediately at the site of injection. The same is not necessarily true of peptide immunogens, which are taken up by specialized antigen presenting cells that then migrate to the draining lymph nodes to present antigen to T cells. At least because of this difference in the way nucleic acids and peptide antigens are taken up by cells following injection (and in addition to the importance of coupling of agents as demonstrated by Shirai *et al.*), the skilled artisan would not reasonably expect nucleic acid and peptide, separately administered at closely adjacent sites, to reach the same cells to effect a corresponding physiological response.

14. The understanding in the art as summarized in ¶¶12 and 13 above is consistent with the teachings of the references cited in the Office Action. US 5,942,607 ("Freeman *et al.*") suggests to the skilled artisan sequential *in vitro* transfection of cells with B7 DNA and pulsing with peptide, followed by introduction of these cells into the host mammal. This method does not teach or suggest separate administration of two agents *in vivo*, and avoids the perceived disadvantage of such separate administration as discussed in ¶¶12 and 13. Moreover, the fact that Freeman *et al.* make the effort to transfect the cells would imply to someone of skill in the art that it was not expected that injection of these agents at separate sites would be effective.

15. None of the other references, cited in the Office Action, would suggest to the skilled artisan to administer Freeman *et al.*'s B7 DNA and peptide antigen separately at closely adjacent sites *in vivo*. Several deficiencies of the other cited references with regard to this proposed modification of Freeman *et al.* are summarized below in ¶¶16-24.

16. At the time of filing of the instant application, for *in vivo* administration of two separate agents targeting the same cell, it was typical to use the agents together as an admixture, rather than as individual formulations administered separately. In the absence of any

SAMIR KLEIF *et al.*
Application No. 09/810,310

PATENT

specific teaching or suggestion to the contrary, and assuming (for argument's sake) a general teaching of *in vivo* administration, one of skill in the art would be led to administer Freeman's B7 DNA and peptide antigen molecules together as an admixture, or coupled, but not separately.

17. None of the cited references teach or suggest to the skilled artisan the administration of two agents separately at closely adjacent sites.

18. In Kaufmann *et al.*, B7.1 DNA is introduced into HPV E7 antigen expressing cervical carcinoma cells (*i.e.*, into cells already expressing target peptide antigen) *in vitro*. Because Kaufmann *et al.* targets cells already expressing antigen, Kaufmann *et al.* do not address co-administration of B7.1 DNA and antigenic peptide. Nor do Kaufmann *et al.* address issues pertaining to *in vivo* administration. Indeed, the fact that Kaufmann *et al.* make the effort to transfect the cells would imply to someone of skill in the art that it was not expected that injection of these agents at separate sites would be effective, but rather that the antigen and B7.1 need to be expressed in the same cell.

19. Rock *et al.* pertains to an analysis of the optimal length of CTL peptides for binding to MHC class I molecules and does not address introduction of B7 DNA into cells.

20. US 5,738,852 ("Robinson *et al.*") discusses administration of polynucleotides encoding a co-stimulatory molecule and polypeptide antigen. Robinson states that the sequences encoding the co-stimulatory molecule and peptide antigen can be on separate polynucleotides, but "preferably are on the same polynucleotide" (*see* col. 10, ll. 36-39). Moreover, for *in vivo* administration, Robinson again points to a single polynucleotide encoding both polypeptides as preferred (*see* col. 13, ll. 41-48). Robinson does not specifically address how to administer separate polynucleotides encoding co-stimulatory molecule and peptide antigen. Nowhere does Robinson teach or suggest to the skilled artisan *in vivo* administration of two polynucleotides separately at closely adjacent sites for achieving expression of B7 and peptide antigen in an APC. In light of the art-recognized mode for administering agents targeting the same cell as an admixture, Robinson would suggest to the skilled artisan

SAMIR KLEIF *et al.*
Application No. 09/810,310

PATENT

administration of individual polynucleotides (encoding co-stimulatory molecule and peptide antigen) as an admixture, and not separately.

21. WO 98/04705 ("Balloul *et al.*") discusses a composition comprising HPV polypeptides and B7.1, or one or more vectors encoding these polypeptides. Balloul's discussion of HPV antigen and B7.1, or vectors encoding these, as components of a "composition" would suggest to the skilled artisan the use of these agents as an admixture. Balloul does not teach or suggest to the skilled artisan *in vivo* administration of these polypeptides or vectors separately at closely adjacent sites.

22. US 6,338,947 ("Sahin *et al.*") discusses pharmaceutical formulations that combine antigenic peptides, or DNA encoding antigenic peptides, with co-stimulatory molecules. Sahin's brief reference to combining antigen with co-stimulatory molecules, which is in the specific context of "formulations" for administering peptide antigen (*see* col. 12, ll. 17-21), would suggest to the skilled artisan the use of peptide antigen (or encoding DNA) with co-stimulatory molecule as an admixture. Sahin *et al.* does not teach or suggest to the skilled artisan *in vivo* administration of the co-stimulatory molecules and antigenic peptides separately at closely adjacent sites.

23. US 6,045,802 ("Schlom *et al.*") discusses an admixture of a recombinant vaccinia virus (rV) expressing a tumor-associated antigen and an rV expressing B7. Schlom *et al.* do not teach or suggest to the skilled artisan *in vivo* administration of the rV encoding antigen and rV encoding B7 separately at closely adjacent sites.

24. Harlow and Lane discuss migration of subcutaneously injected immunogens to the draining lymph nodes closest to the site of injection, but does not address co-administration of DNA with peptide antigens, whether as an admixture or separately.

25. The skilled artisan, considering the teachings of Shirai *et al.* (*see* ¶12) together with the difference in the way nucleic acids and peptide antigens are taken up by cells following injection (*see* ¶13), and further considering the lack of any demonstration or discussion in the cited art of administering peptide and vector separately to closely adjacent sites (*see* ¶¶14-

SAMIR KLEIF *et al.*
Application No. 09/810,310

PATENT

24), would not have a reasonable expectation of success for inducing an immune response by separate administration of a peptide antigen and B7-encoding nucleic acid to closely adjacent sites.

26. I understand that the Examiner asserts the following as proposed motivations to achieve the claimed invention based on the references discussed above in ¶¶ 18-24:

- (a) in order to enhance a CTL response;
- (b) it was desirable to use an adjuvant with peptide antigens (citing Sahin *et al.*);
- (c) the immune response that ensues from expression of both antigen and B7 in an APC (citing Robinson *et al.*), together with the knowledge that s.c.-injected immunogens drain into lymph nodes closest to the injection site (citing Harlow and Lane); and
- (d) using an admixture of vector encoding antigen and vector encoding B7 can lead to co-infection of, and co-expression in, APCs to enhance T cell response (citing US 6,045,802).

27. None of the proposed motivations enumerated by the Examiner and summarized in ¶26 are specific enough or have sufficient force to lead one of ordinary skill in the art to the particular invention as presently claimed in the application. These proposed motivations do not specifically lead the artisan to administration of a peptide antigen and nucleic acid encoding B7 separately at closely adjacent sites, for at least the reasons discussed in ¶¶ 28-32 below.

28. With regard to the Examiner's proposed motivation (a) as summarized in ¶26, the cited references generally show induction of CTL responses without separate

SAMIR KLEIF *et al.*
Application No. 09/810,310

PATENT

administration of agents to closely adjacent sites. Each of the cited references that pertain to the use of both a peptide antigen and a co-stimulatory molecule discusses a specific and self-sufficient strategy for inducing an immune response. The cited references do not provide any teaching or suggestion as to how separate administration of the disclosed agents to closely adjacent sites would in any way improve the strategies discussed. Therefore, the desire to induce an immune response, by itself, would not provide a specific suggestion to the skilled artisan to modify the references as proposed by the Examiner.

29. With regard to the Examiner's proposed motivation (b) as summarized in ¶26, it was generally well-known to use adjuvants as an admixture with peptide antigens, *i.e.*, as part of the same formulation. Therefore, assuming that a skilled artisan would be impelled to modify the references so as to use a B7-encoding nucleic acid as an adjuvant with peptide antigen for *in vivo* administration, the skilled artisan reading the cited references would be led to use these agents as an admixture, and not for separate injection.

30. With regard to the Examiner's proposed motivation (c) as summarized in ¶26, the migration of s.c.-injected immunogens to the draining lymph nodes closest to the injection site does not suggest to the skilled artisan any particular advantage in separate *in vivo* administration of peptide antigen and B7-encoding vector, particularly in view of (i) Robinson's teaching that it is preferred to use a single polynucleotide encoding both co-stimulatory molecule and antigen; (ii) Robinson's silence on the issue of how to administer separate polynucleotides, together with the art-recognized mode for administering agents targeting the same cell as an admixture; and (iii) the teachings or suggestions in other references cited by the Examiner (*e.g.*, Balloul *et al.*, Sahin *et al.*, Schlom *et al.*) pointing to *in vivo* administration of two agents either coupled or as an admixture.

31. With regard to the Examiner's proposed motivation (d) as summarized in ¶26, the admixture of polynucleotides encoding antigen and B7 does not teach or suggest to the skilled artisan the use of these agents for separate *in vivo* administration. The Examiner states that US 6,045,802 discloses "injection of the two molecules separately." I understand the Examiner to be using the term "separately" in reference to the use of two polynucleotides that are

SAMIR KLEIF *et al.*
Application No. 09/810,310


PATENT

not covalently linked on the same vector but still used as an admixture, in light of both the Examiner's acknowledgement that the '802 patent discloses the use of the two polynucleotides as an admixture, as well as the '802 patent's lack of any discussion regarding the administration of the two polynucleotides other than on the same vector or as an admixture.

32. As previously discussed in ¶¶12 and 13 above, there would not be a reasonable expectation that separately administered peptide antigen and DNA encoding B7 would have sufficient access to the same cells to achieve an immune response. A lack of sufficient access to the same cells *in vivo* would be regarded by the skilled artisan as a disadvantage to the use of separate administration of peptide antigen and B7 nucleic acid to closely adjacent sites. The art suggests that cells in the immediate region of the injection site take up DNA while peptide can be found well-dispersed from the injection site, such as in the draining lymph nodes. This perceived disadvantage would lead the skilled artisan away from the use of separate administration as presently claimed.

33. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that I make these statements with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements my jeopardize validity of the application or any patent issuing therefrom.

Executed this 18th day of August, 2006

By: 

Name: Jay Berzofsky

Title: Chief, Vaccine Branch
CCR, NCI, NIH



CURRICULUM VITAE

Name: Jay Arthur Berzofsky

Date and Place of Birth: April 13, 1946, Baltimore, Maryland

Marital Status: Married to Sharon M. Miller; two children
Alexander, April 30, 1974, and Marcus, May 27, 1976

Education:

1967 - A.B., Harvard University (Summa Cum Laude in Chemistry)
1971 - Ph.D., Albert Einstein College of Medicine, Molecular Biology
1973 - M.D., Albert Einstein College of Medicine, Medical Scientist
Training Program

Brief Chronology of Employment:

1973 - 1974	Medical Internship (Straight Medicine), Massachusetts General Hospital, Boston, Massachusetts
1974 - 1976	Research Associateship, Laboratory of Chemical Biology National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health
1976 - 1979	Investigator ("Expert"), Metabolism Branch, National Cancer Institute, National Institutes of Health
1979 - 1987	Senior Investigator, Metabolism Branch, National Cancer Institute, National Institutes of Health
1987 - 2003	Chief, Molecular Immunogenetics and Vaccine Research Section, Metabolism Branch, National Cancer Institute, National Institutes of Health
2004 - Date	Chief, Vaccine Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health

Honors/Awards:

Detur Prize, Harvard University, 1964
Harvard College Scholarship, Harvard University, 1964
Phi Beta Kappa, Junior Year, Harvard University, 1966
Summa Cum Laude in Chemistry, Harvard University, 1967
Sophia Freund Prize for Graduate with Highest Cumulative Grade Point
Average, Harvard College, 1967
NIH Special Achievement Award, 1982
Hollister - Stier's Distinguished Lectureship, Washington State

University, 1986
 J. W. McLaughlin Fund Distinguished Contributions to Immunology Lectureship,
 University of Texas Medical School, Galveston, 1987
 U. S. Public Health Service Superior Service Award, 1988
 31st Michael Heidelberger Award and Lecture, Columbia University, 1992
 McLaughlin Visiting Professorship, University of Texas Medical School,
 Galveston, 1992
 American Society for Clinical Investigation, President 1993-94
 Fellow of the American Association for the Advancement of Science, 1995
 Cytokine Interest Group Best Paper of 2000 Award to fellow in lab, 2001
 The 2004 Tadeusz J. Wiktor Memorial Lecture, Wistar Institute, University of
 Pennsylvania, Philadelphia, PA., November 17, 2004
 Chair-elect, Medical Sciences Section, American Association for the Advancement of
 Science, 2006-2007
 Distinguished Alumnus of the Year Award 2007, Albert Einstein College of Medicine

Professional Society Memberships:

Association of Harvard Chemists, 1967 - present
 New York Academy of Sciences, 1971 - present
 American Association of Immunologists, 1977 - present
 Undersea Medical Society, 1978 - 1988
 American Federation for Clinical Research, 1979 - present
 American Society of Biological Chemists, 1980 - present
 American Society for Clinical Investigation, 1983 - present,
 Secretary-Treasurer, 1989 - 1992
 President-elect, 1992-1993
 President, 1993-94
 Association of American Physicians, 1990 – present
 American Association for the Advancement of Science, Chair-elect of Medical
 Sciences Section, 2006-2007

Editorial Positions:

Associate Editor, *Journal of Immunology*, 1980 - 1984
 Editorial Advisory Board, *Journal of Molecular and Cellular Immunology*, 1983-88
 Advisory Editor, *Molecular Immunology*, 1985 - 1988
 Editorial Board, *Peptide Research*, 1987 - present
 Transmitting Editor, *International Immunology*, 1988 - 2000
 Editorial Board, *Journal of Human Virology*, 1997-present
 Consulting Editor, *Journal of Clinical Investigation*, 1998-2005
 Section Editor, *Clinical Immunology*, 2002-present
 Associate Editor, *Clinical Cancer Research*, 2002-present

Professional Committees and Activities:

American Association of Immunologists, Membership Committee, 1981 - 1988
 American Association of Immunologists, Chairman of Membership Committee,
 1983 - 1988

NIH Clinical Center Compensable Events Committee, 1982 - present
 American Society for Clinical Investigation, Council, 1989-1994
 NCI Division of Clinical Sciences Promotion and Tenure Committee, 1995-2001.
 NCI Division of Clinical Sciences Research Advisory Group, 1995-2001
 NCI Director's Intramural Advisory Board, 1997-99
 NIH AIDS Vaccine Research Center Steering Committee, 1997-present
 NIH Search Committee for Director of Office of AIDS Research, 1997-98
 NIAID Malaria Vaccine Task Force, 1998-present
 NCI Vaccine Working Group, Chairman/Organizer, 1998-present
 NCI/CCR Immunology Faculty Steering Committee, 2001-present
 NCI/CCR HIV & Virology Faculty Steering Committee, 2001-present
 NCI/CCR Frontiers in Science Newsletter Editorial Board, 2001-present.
 NCI/NIH Committee for Biodefense, founding member, 2001-present.
 NCI Center of Excellence in Immunology, Steering Committee, 2003-present.
 NIH CRADA 01361 with Genzyme Corporation. Co-principal Investigator, 2003-present
 Advisory Committee, Harvard Blood Center, 2004-present
 External Advisory Committee, University of London, 2006-present.

Military Service:

Commissioned Corps, United States Public Health Service, 1974 - 1976

Other Research Experience:

Summers, 1962 - 1965 Research Assistant, Pediatric Research Unit (H. M. Nitowsky), Sinai Hospital, Baltimore, Maryland
 Summer, 1966 Research Assistant, Organic Synthesis Laboratory (C. H. Robinson), Department of Pharmacology, Johns Hopkins School of Medicine, Baltimore, Maryland
 Summer, 1967 Visiting Scientist, Laboratoire d'Enzymologie (G. N. Cohen), Centre National de la Recherche Scientifique, Gif-sur-Yvette, France

Medical Licensure: Maryland and Massachusetts

Major Outside Activities (Not permitted by NIH after 2005)

Medimmune, Inc.—Scientific Founder and Chair, Scientific Advisory Board, 1989-2002
 Magainin Pharmaceuticals, Inc.—Member, Scientific Advisory Board, 1991-97
 Diacrin, Inc.—Member, Scientific Advisory Board, 1993-2002
 Pharmadyne, Inc.—Scientific Co-Founder and Chair, Scientific Advisory Board, 1997-2004
 Boston University Community Technology Fund—Consultant, 1997-1999
 Health Care Ventures, Inc.—consultant, 1998
 EMD Pharmaceuticals, Inc.—consultant, 2000-2003
 Epivax, Inc.—Member, Scientific Advisory Board, 2000-2004
 Therapeutic Devices, Inc.—consultant, 2002-2004
 Transform Pharmaceuticals, Inc.—consultant 2002-2005
 Celera Genomics, Inc.—consultant 2002-2004
 Genencor International, Inc.—consultant 2003-2004.

Major areas of research:

1. Molecular basis of antigen recognition by T lymphocytes
2. Processing of antigens and their presentation by major histocompatibility molecules
3. Structure of antigenic sites on protein antigens
4. Genetic regulation of the immune response
5. Design and development of artificial vaccines based on immunological principles and peptide synthesis or recombinant DNA technology
6. AIDS vaccines and diagnostic techniques
7. Malaria vaccines
8. Cancer vaccines
9. Antigen-antibody interactions
10. Structure-function relationships in proteins and protein conformation.
11. Regulation of tumor immunosurveillance and T cell function by cytokines
12. Mucosal immunity and vaccines

BIBLIOGRAPHY

Jay Arthur Berzofsky

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- 12 Sachs, D.H., J.A. Berzofsky, C.G. Fathman, D.S. Pisetsky, A.N. Schechter, and R.H. Schwartz. 1976. The immune response to staphylococcal nuclease: A probe of cellular and humoral antigen specific receptors. *Cold Spring Harbor Symp. Quant. Biol.* 41:295-306.
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
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Patent Applications Filed, Patents Issued & Technology Transfer

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- Berzofsky, J. A., Ouyang, C. S., DeLisi, C., Margalit, H., Cornette, J. L., and Cease, K. B. Synthetic peptides which induce cellular immunity to the AIDS virus and AIDS viral proteins. Filed December 30, 1986. Application No. 06/947,935. CIP 07/492,318. Patent 5,081,226 issued January 14, 1992.
- Good, M. F., Berzofsky, J. A., and Miller, L. H. Improved malarial immunogen. Filed February 26, 1987. Application No. 07/019,000. Patent Number 4,886,782 issued December 12, 1989.
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- Berzofsky, J. A., Hale, P. M., Hosmalin, A., Margalit, H., Spouge, J. L., and Cornette, J. L. Synthetic vaccine against AIDS virus. Filed July 21, 1988. Application No. 07/222,684. Patent 5,030,449 issued July 9, 1991.
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- Berzofsky, J. A. Multideterminant peptide antigens that stimulate helper T lymphocyte response to HIV in a range of human subjects. Filed August 29, 1991. Application No. 07/751,998. Patent 5,939,074 issued August 17, 1999.
- Berzofsky, J. A., Takahashi, H., and Germain, R. N. Method to induce cytotoxic T lymphocytes specific for a broad array of HIV-1 isolates using hybrid synthetic peptides. Filed September 18, 1991. Application No. 07/760,530. Patent 5,711,947 issued January 27, 1998; Patent 5,820,865 issued October 13, 1998.
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- Shearer, G.M., Berzofsky, J.A., and Clerici, M. Test of HIV-specific T lymphocyte function that detects exposure to HIV antigens and possibly early HIV infection. Filed May 14, 1992. Application No. 07/882,078.
- Berzofsky, J.A., Shirai, M., Akatsuka, T., and Feinstone, S.M. Identification of peptides that stimulate hepatitis C virus specific cytotoxic T cells. Filed June 10, 1992. Application 07/894,063. Patent 5,980,899 issued Nov. 9, 1999.
- Berzofsky, J.A., Yanuck, M., Takahashi, H., Carbone, D.P., and Minna, J.D. Novel Immunotherapeutic Methods and Vaccines. Filed March 15, 1993. Application No. 08/031,494.
- Berzofsky, J.A., Ahlers, J.D., Pendleton, C.D., Nara, P., and Shirai, M. Composite synthetic peptide construct eliciting neutralizing antibodies and cytotoxic T lymphocytes against HIV. Filed May 14, 1993. Application No. 08/060,988. U. S. Patent 5,932,218 issued August 3, 1999. European Patent 0701572 B1, issued August 11, 1999. Divisional: Multideterminant peptides that elicit helper T lymphocyte, cytotoxic T lymphocyte, and neutralizing antibody responses against HIV-1. U.S. Patent 6,294,322 B1 issued Sept. 25, 2001.
- Berzofsky, J.A., Feinstone, S., and Shirai, M. Hepatitis C virus core peptide for stimulation of cytotoxic T lymphocytes and diagnosis of HCV exposure. Filed April 8, 1994. Application No. 08/224,973. European patent 0754193 issued June 14, 2000.
- Goletz, T.J., Berzofsky, J.A., and Helman, L.J. Novel immunotherapeutic methods and vaccines. Filed September 15, 1995. Application No. 08/528,129. Notice of allowance April 14, 1999. U.S. Patent 5,997,869 issued December 7, 1999.
- Klimpel, K., Goletz, T.J., Arora, N., Leppla, S.H., and Berzofsky, J.A. Targeting antigens to the MHC class I processing pathway with an Anthrax toxin fusion protein. Filed September 17, 1996. Application No. 60/025,270. US Patent 6,592,872 issued July 15, 2003.
- Berzofsky, J.A., Belyakov, I.M., Derby, M.A., Kelsall, B.L., and Strober, W. Mucosal cytotoxic T lymphocyte responses. Filed September 11, 1997. Application 60/058,523. Divisional 10/815,340 filed April 15, 2004. Patent 6,749,856 issued June 15, 2004. European Patent 1011720 issued Dec. 29, 2004.
- Berzofsky, J.A., Sarobe, P., Major, M., Feinstone, S.H. Modified HCV peptide vaccine. Filed Aug. 21, 1998. Application 60/097,446. Application 09/763,260 filed Oct. 19, 2001 as continuation. US Patent 6,685,944 issued February 3, 2004.
- Berzofsky, J. A., M. Terabe, D. D. Donaldson, S. Matsui, N. Noben-Trauth, and W. E. Paul. Method and composition for enhancing an immune response. Filed October 20, 2000. Application 90/693,600.
- Terabe, M., S. Matsui, J.A. Berzofsky. Methods to Prevent Tumor Recurrence by Blockage of TGF-Beta. Application US 60/421,286. Filed October 25, 2002. PCT International Application PCT/US03/34023 Filed October 24, 2003.

- Morris, J., J.A. Berzofsky, Y. Sakai, J.-M. Park, M. Terabe. Methods for Prophylaxis and Treatment of HER-2/neu Tumors. Provisional application filed 2002.
- Perera, L. P., T. A. Waldmann, S. Oh, J. A. Berzofsky. Recombinant Vaccinia Viruses Expressing IL-15 and Methods of Using the Same. Application #: U.S. Provisional 60/433,703. Filed December 16, 2002.
- Berzofsky, J. A., and T. Okazaki. Enhanced HIV-1 Vaccines and Methods for Their Use. U.S. Provisional Application 60/459,507, filed March 31, 2003.
- Berzofsky, J.A., I. Pastan, S. Oh. Immunogenic Peptides and Peptide Derivatives for Prostate and Breast Cancer Treatment. Application # 60/476,467. Filed June 5, 2003. National Stage US Patent Application 10/559,329 filed December 2, 2005.
- Berzofsky, J.A., J. T. Snyder, II, A. Dzutsev, and I. M. Belyakov. Peptides for the induction of an immune response to vaccinia virus and their use. Application 60/512,039. Filed October 16, 2003.
- Berzofsky, J.A., I. H. Pastan, and M. Terabe. Immunogenic peptides of XAGE-1. Application # 60/529,025. Filed December 12, 2003. International PCT/US2004/041639 filed December 13, 2004.
- Berzofsky, J.A., and T. Okazaki. Epitope-Enhancement of a Human CD4 HIV Epitope. Application # 60/567,073, filed on April 30, 2004
- Catanzaro, A., R. Yarchoan, J. A. Berzofsky, T. Okazaki, J. T. Snyder, and S. Broder. Vaccines and Methods for Prevention and Treatment of Drug-Resistant HIV-1 and Hepatitis B Virus. Application 60/655,984 pending, filed Feb. 22, 2005.
- Terabe, M., S. Takaku, and J. A. Berzofsky. Synergistic effect of TGF-beta blockade and immunogenic agents on tumors. U.S. Patent Application No. 60/654,329, filed February 17, 2005.
- NIH CRADA 01361 with Genzyme Corporation (2003-date). Co-principal Investigator

Jay A. Berzofsky
Speaking and Chairmanship Invitations
1990-2005

1990

27 Jan.-3 Feb., 1990 UCLA Symposium on Cellular Immunity and the Immunotherapy of Cancer, Park City, Utah. Invited plenary session speaker.

5 Feb., 1990 Walter Reed Army Institute of Research AIDS Conference, Washington, D.C., Invited speaker.

2 March, 1990 University of Pennsylvania School of Medicine, Philadelphia, PA, seminar speaker.

1-7 April, 1990 UCLA Symposium on HIV and related Retroviruses, Keystone, CO. Invited plenary session speaker.

3-7 June, 1990 American Association of Immunologists, FASEB, Meeting, New Orleans, LA. Invited symposium chairperson (Antigen Processing and Presentation) and symposium speaker.

20-24 June, 1990 Sixth International Conference on AIDS, San Francisco, CA. Invited plenary session speaker on Vaccines.

8-12 July, 1990 Symposium on Antigen Presenting Cells organized by the University of Vienna, Baden bei Wien, Austria. Invited speaker.

11-17 Aug., 1990 Laboratory of Tumor Cell Biology Meeting on AIDS and Human Retroviruses, Bethesda, Md. Invited speaker and session chairperson.

9-12 Sept., 1990 European Federation of Immunological Societies Meeting, Edinburgh, Scotland, U.K. Invited plenary session speaker.

19 Oct., 1990 University of Massachusetts Medical School, Worcester, MA. Invited seminar speaker.

29-30 Oct., 1990 NCI Cancer Vaccine Workshop, Bethesda, MD. Invited speaker.

15-16 Nov., 1990 New Horizons in Immunology Symposium, organized by *Nature*, Boston, MA. Invited speaker.

4 Dec., 1990 National Academy of Sciences Institute of Medicine Meeting on Malaria, Washington, D. C. Invited speaker.

1991

12-17 March, 1991 Keystone Symposium on Immunotoxins, Denver, CO. Invited Plenary Speaker.

17 April, 1991 Harvard Medical School, Immunology Program, Boston, MA. Invited speaker.

3-6 May, 1991 Association of American Physicians, Seattle, WA. HIV session speaker.

17-18 May, 1991 Columbia University/Progenics Conference on AIDS, Arden House, NY.
Invited speaker.

16-21 June, 1991 7th International Conference on AIDS, Florence, Italy. Invited speaker.

1-8 Sept., 1991 Laboratory of Tumor Cell Biology Retrovirus Meeting, Bethesda, MD.
Invited speaker and session chairperson.

19-23 Sept., 1991 Cold Spring Harbor Vaccine Conference, Cold Spring Harbor, NY.
Invited opening speaker.

15-19 Oct., 1991 Queensland Institute for Medical Research, Bancroft Center Opening
Symposium, Brisbane, Queensland, Australia. Invited Plenary Keynote Speaker.

15 Nov., 1991 NIH Technology Transfer Symposium, Bethesda, MD. Invited speaker.

22 Nov., 1991 University of Virginia School of Medicine, Dept. of Microbiology,
Charlottesville, VA. Invited speaker.

1992

10 January, 1992 Uniformed Services University of the Health Sciences, Bethesda, MD.
Immunology course guest lecturer on Ir genes, and antigen processing and presentation.

4 February, 1992 National Cancer Institute, Experimental Immunology Branch, Bethesda,
MD. Invited guest seminar speaker.

12 February, 1992 National Institute of Diabetes, Digestive, and Kidney Diseases, Laboratory
of Chemical Biology, Bethesda, MD. Invited seminar speaker.

27 Mar.-4 Apr., 1992 Keystone Symposium on Prevention and Treatment of AIDS, Keystone,
CO. Invited plenary speaker.

27 May, 1992 Columbia University College of Physicians and Surgeons, New York, NY.
31st Michael Heidelberger Award and Lecture.

5 June, 1992 Tufts University School of Medicine, Department of Medicine, Boston,
MA. Invited Grand Rounds speaker.

13 July, 1992 National Cancer Institute, Laboratory of Tumor Cell Biology, Bethesda,
MD. Invited seminar speaker.

9-16 Aug., 1992 National Cancer Institute, LTCB Annual Symposium on Human
Retroviruses, Bethesda, MD. Invited speaker and session chairperson.

- 23-28 Aug., 1992 8th International Congress of Immunology, Budapest, Hungary. Invited chairperson of Workshop on Antigen Processing and Presentation, and speaker.
- 29-31 Aug., 1992 Symposium on Prediction and Recognition of Antigenic Determinants, Eötvös University, Budapest, Hungary. Invited plenary speaker and chairperson.
- 21-22 Sept., 1992 NIH Research Festival, Bethesda, MD. Invited session chairperson and speaker.
- 19-20 Oct., 1992 University of Texas Medical Branch, Galveston, TX. McLaughlin Visiting Professor.
- 20-23 Oct., 1992 54th Annual MD Anderson Symposium on the Immunobiology of Cancer, Houston, TX. Invited plenary speaker.
- 1993**
- 21-24 Jan., 1993 New York Academy of Sciences Symposium on the Specific Immune Treatment of Cancer, Washington, DC. Invited plenary speaker.
- 8-14 Feb., 1993 Keystone Symposium on Antigen Processing and Presentation, Taos, NM, Invited plenary speaker.
- 17-24 March, 1993 Joint Keystone Symposia on Cellular Immunity and Immunotherapy of Cancer, and on the Molecular Immunology of Virus Infections, Taos, NM. Invited joint plenary session speaker.
- 19-29 April, 1993 CBER-FDA Workshop on HIV Vaccines, Bethesda, MD. Invited speaker.
- 28-30 July, 1993 FDA Workshop on Combination Vaccines, Bethesda, MD. Invited speaker.
- 22-28 Aug., 1993 Laboratory of Tumor Cell Biology Annual Retrovirus Meeting, Bethesda, MD. Invited speaker and chairperson.
- 20-24 Sept., 1993 Cold Spring Harbor Symposium on Vaccines including the Prevention and Treatment of AIDS, Cold Spring Harbor, NY. Invited opening plenary speaker.
- 1-4 Nov., 1993 National Cooperative Vaccine Development Meeting on Advances in AIDS Vaccine Development, Division of AIDS, NIAID, Alexandria, VA. Invited speaker.
- 5-7 Nov., 1993 Project Inform/Immune Restoration Think Tank on HIV Treatment, Baltimore, MD. Invited Discussant.

10 Dec., 1993 Institute of Medicine Symposium "Towards an Understanding of the Correlates of Protective Immunity to HIV Infection," Washington, DC. Invited participant.

1994

23-30 Jan., 1994 Keystone Symposium on HIV, Hilton Head Island, SC. Invited plenary speaker.

13-30 Feb., 1994 Keystone Symposium on Human Tumor Viruses, Taos, NM. Invited plenary speaker.

29 Apr.-2 May, 1994 American Society for Clinical Investigation, Baltimore, MD. Presidential address.

18-19 July, 1994 Conference on Novel HIV Vaccine Strategies, Washington, D.C. Invited plenary speaker.

19-21 Sept., 1994 NIH Research Festival, Bethesda, MD. Invited speaker.

25-30 Sept., 1994 Laboratory of Tumor Cell Biology Annual Retrovirus Meeting, Bethesda, MD. Invited speaker and chairperson.

5-9 Oct., 1994 Cold Spring Harbor Meeting on Molecular Approaches to the Control of Infectious Diseases, Cold Spring Harbor, NY. Invited keynote speaker.

1995

16-23 Jan., 1995 Keystone Symposium on Molecular Aspects of Viral Immunity, Keystone, CO. Invited plenary speaker.

25-27 Jan., 1995 Jennifer Jones Simon Foundation Workshop on Cancer Immunotherapy, Los Angeles, CA. Invited discussant.

29 Jan-2 Feb, 1995 American Society for Microbiology Second National Conference on Human Retroviruses and Related Infections, Washington, DC. Invited speaker.

9 Feb., 1995 National Cancer Institute, Pediatric Oncology Branch, NIH, Bethesda, MD. Invited seminar speaker.

3-5 Mar., 1995 Second International Conference on Engineered Vaccines for AIDS and Cancer, San Francisco, CA. Invited plenary speaker.

- 19 May, 1995 University of Michigan, Dept. of Medicine, Ann Arbor, MI. Ground Rounds speaker.
- 23-29 July, 1995 9th International Congress of Immunology, San Francisco, CA. Invited plenary symposium chairperson and speaker.
- 27 Aug-2Sept, 1995 Laboratory of Tumor Cell Biology Annual Retrovirus Meeting, Bethesda, MD. Invited chairperson and speaker.
- 6-9 Sept., 1995 Queensland Institute for Medical Research Golden Jubilee Symposium, Brisbane, Australia. Invited plenary speaker.
- 10-23 Sept., 1995 Australasian Society for Immunology Visiting Speaker, Melbourne, Canberra, and Sydney, Australia, and Dunedin and Auckland, New Zealand.
- 10 Nov., 1995 Emory University, Dept. of Microbiology and Immunology, Atlanta, GA. Invited seminar speaker.
- 30 Nov-3 Dec, 1995 First International Antigen Processing and Presentation Conference: Fundamental Mechanisms and their Application, Los Angeles, CA. Invited speaker.
- 16-19 Dec., 1995 Winter Advanced Course in Immunology and Infectious Disease, Tsuruoka, Japan. Invited faculty member/speaker.
- 1996**
- 26-27 Feb., 1996 IBC Vaccine Technology Conference, Washington, DC. Invited speaker
- 25 Mar., 1996 CHI Symposium on New Cancer Strategies: p53 Diagnostics and Therapy, Washington, DC. Invited speaker.
- 26 Mar., 1996 Institute of Medicine Vaccine Workshop, Washington, DC. Invited speaker.
- 17-20 Apr., 1996 British Society for Immunology Jenner Bicentenary Symposium, Bristol, UK. Invited plenary speaker.
- 7-13 Sept., 1996 Institute of Human Virology Annual Retrovirus Meeting, Baltimore, MD. Invited speaker.
- 1-3 Oct., 1996 NIH Intramural Immunology Retreat, Airlie, VA. Invited workshop chair.
- 25-27 Oct., 1996 University of Rome Cancer Immunotherapy Symposium, Rome, Italy. Invited speaker.
- 23-27 Nov., 1996 Japan Immunology Society Jenner Bicentenary Symposium, Yokohama, Japan. Invited plenary speaker.

- 18-22 Oct., 1998 5th International Union of Biochemistry and Molecular Biology
Conference on the Biochemistry of Health and Disease, Jerusalem, Israel. Invited
Symposium Speaker.
- 25 Oct., 1998 Weizmann Institute of Science, Rehovot, Israel, Invited seminar speaker.
- 26 Oct., 1998 University of London Medical School, Guy's Hospital, Invited seminar
speaker.
- 1-6 Nov., 1998 10th International Congress of Immunology, New Delhi, India. Invited
Symposium Speaker.
- 18-20 Nov., 1998 NMHCC Conference on Functional Antigenics, Washington, D.C. Invited
speaker.
- 10-11 Dec., 1998 FDA-NCI Workshop on Tumor Vaccines, Bethesda, MD. Invited speaker.

1999

- 7-13 Jan., 1999 Keystone Symposium on HIV Vaccine Development, Keystone, CO.
Invited speaker
- 16 March, 1999 University of Pittsburgh School of Medicine, Invited seminar speaker
- 12-17 April, 1999 Keystone Symposium on DNA Vaccines, Snowbird, Utah. Co-organizer
and invited plenary speaker.
- 21-23 April, 1999 5th National Symposium on the Basic Aspects of Vaccines, Bethesda,
MD. Invited plenary session chair and speaker.
- 6 May, 1999 Workshop on Alloimmunization as a Strategy for Vaccine Design against
HIV/AIDS, Bethesda, MD. Invited speaker.
- 7-9 June, 1999 6th International Symposium on Hepatitis C and Related Viruses, Bethesda, MD.
Invited plenary speaker.
- 30 Aug-3 Sept 1999 Institute of Human Virology Annual Meeting, Baltimore, MD. Invited
State-of-Art Lecturer
- 8-10 Sept., 1999 International Congress on Cytokines, Bethesda, MD. Invited speaker.
- 13 Dec., 1999 Hôpital Cochin INSERM Unit, Paris, France. Invited seminar speaker.
- 13-15 Dec., 1999 Club Francophone des Cellules Dendritiques Symposium, Paris, France.
Invited plenary speaker.

2000

- 21-27 Jan., 2000 Keystone Symposium on Cellular Immunology and Immunotherapy of
Cancer, Santa Fe, NM, Invited Workshop Chairperson and speaker.
- 8-12 March, 2000 2nd Sabin Vaccine Foundation Walker's Cay Colloquium on
Immunotherapy of Cancer, Invited Speaker
- 6 April, 2000 New York Blood Center, New York, NY. Invited seminar speaker.
- 3-5 May, 2000 6th National Symposium on the Basic Aspects of Vaccines, Bethesda,
MD. Invited plenary session chair and speaker.
- 11 May, 2000 NIH Cytokine Symposium, Bethesda, MD. Invited Speaker
- 12-16 July, 2000 Mid-Summer Symposium on Hepatitis C Virus Vaccines, Jamaica.
Invited speaker and session organizer/chair

- 10-15 Sept., 2000 Inst. of Human Virology Annual Mtg, Baltimore, MD. Invited State-of-Art Lecturer
- 22 Sept., 2000 NCI Symposium on Bench to Bedside and Back, Basic and Translational Biomedical Research, Bethesda, MD. Organizer and Chair.
- 2 Nov., 2000 NIH Collaborative Meeting on HIV Vaccines, Bethesda, MD. Invited Speaker.
- 7-8 Dec., 2000 Forum for Collaborative HIV Research/ George Washington University Workshop on Immune-Based Therapies and HIV Disease, Washington, DC. Invited discussant.
- 2001**
- 10 January, 2001 Institute of Human Virology, Baltimore, MD. Invited seminar speaker.
- 17-18 Jan., 2001 Genetics Institute, Cambridge, MA. Invited seminar speaker.
- 22-27 Jan., 2001 Keystone Symposium on the Interface between Innate and Adaptive Immunity, Keystone, CO. Invited plenary session speaker.
- 4-8 Feb., 2001 8th Conference on Retroviruses and Opportunistic Infections, Chicago, IL. Invited symposium speaker.
- 7-10 Mar., 2001 3rd Walker's Cay Colloquium on Cancer Vaccines and Immunotherapy, Sabin Vaccine Institute, Walker's Cay, Bahamas. Invited speaker.
- 28 Mar.-3 Apr., 2001 Keystone Symposium on AIDS Vaccines in the New Millenium, Keystone, CO. Invited plenary session speaker.
- 1 May, 2001 Vaccine Research Center, NIH, Bethesda, MD. Invited seminar speaker.
- 2-4 May, 2001 7th National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Organizing committee.
- 4-7 May, 2001 Federation of Clinical Immunology Societies (FOCIS) Meeting, Boston, MA. Invited plenary session speaker.
- 2 July, 2001 Celera Genomics, Inc., Rockville, MD. Invited seminar speaker.
- 22-28 July, 2001 11th International Congress of Immunology, Stockholm, Sweden. Invited workshop chair.
- 27 Aug. 2001 IDEC Pharmaceuticals, La Jolla, CA. Invited seminar speaker.
- 9-13 Sept., 2001 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited plenary session speaker.

- 27-31 Oct., 2001 13th Cent Gardes Symposium on Retroviruses of Human AIDS and Related Animal Diseases, Annecy, France. Invited speaker.
- 28 Nov.- 2 Dec., 2001 3rd Midwinter Symposium on Hepatitis C Virus, Barbados. Invited speaker and chairperson.
- 18 Dec., 2001. Pulmonary Branch, National Heart, Lung, & Blood Institute Seminar, Bethesda, MD. Invited speaker.
- 2002**
- 16-22 Jan., 2002 Keystone Symposium on T Lymphocyte Activation, Differentiation, and Death, Keystone, CO. Invited plenary speaker.
- 6-10 March, 2002 Fourth Walker's Cay Colloquium on Cancer Vaccines and Immunotherapy, Walkers Cay, Bahamas. Invited speaker.
- 5-11 April, 2002 Keystone Symposium on HIV-1 Protection and Control by Vaccination, Keystone, CO. Invited plenary speaker.
- 10-15 April, 2002 Keystone Symposium on Gene-Based Vaccines, Breckenridge, CO. Co-organizer and invited plenary speaker.
- 22-24 April, 2002 International Meeting on Cytokines as Natural Adjuvants: Perspectives for Vaccine Development, Rome, Italy. Invited plenary speaker.
- 1-3 May, 2002 8th National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Organizing committee
- 10 May, 2002 International Immunological Readouts Meeting (Workshop), Bethesda, MD. Invited speaker.
- 26 June, 2002 American Association of Immunologists Introductory Course in Immunology, Tufts University, Medford, MA. Invited lecturer.
- 27-31 July, 2002 FASEB Summer Research Conference on Therapeutic and Preventive AIDS Vaccines, Tuscon, AZ. Invited plenary speaker.
- 9-13 Sept., 2002 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited plenary session speaker.
- 23-25 Oct., 2002 DNA Vaccines 2002, Royal College of Physicians, Edinburgh, Scotland. Invited plenary speaker.
- 26-29 Oct., 2002 XIIIth Cent Gardes Meeting on HIV and AIDS Vaccines, Annecy, France. Invited plenary speaker.

- 5-8 Nov., 2002 2nd International Workshop on CD1 Antigen Presentation and NK T Cells, Woods Hole, MA. Invited speaker.
- 18-23 Nov., 2002 BioSecurity 2002: Vaccines: The Paradigm Quake, Las Vegas, NV. Invited speaker.
- 25-27 Nov., 2002 Pan American Health Organization Centennial Celebration Conference on Vaccines, Washington, DC. Invited plenary speaker.

2003

- 7 Jan., 2003 NIH Academy, Invited speaker.
- 15-19 Jan., 2003 AACR Special Conference in Cancer Research: The TGF- β superfamily—roles in the pathogenesis of cancer and other diseases, La Jolla, CA. Invited plenary speaker.
- 23-24 Jan., 2003 AAI/NCI Workshop on Cancer Immunology, Bethesda, MD. Invited participant.
- 27 Jan., 2003 University of Chicago Committee on Immunology Seminars, Chicago, IL. Invited speaker
- 17-23 Feb., 2003 Keystone Symposium on Basic Aspects of Tumor Immunology, Keystone, CO. Invited speaker.
- 5-8 March, 2003 Sabin Vaccine Institute 5th Walker's Cay Colloquium on Cancer Vaccines and Immunotherapy, Walker's Cay, Bahamas. Invited speaker.
- 13 March, 2003 Experimental Transplantation Branch, CCR, NCI, Bethesda, MD. Invited seminar speaker.
- 28 Mar-4 Apr., 2003 Keystone Symposium on HIV Vaccine Development, Banff, Alberta, Canada. Invited speaker.
- 23-24 April, 2003 Kunkel Society of Rockefeller University Annual Meeting, New York, NY. Invited plenary speaker.
- 30 Apr.-2 May, 2003 9th WRAIR National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Organizing committee
- 15-19 May, 2003 3rd Annual Meeting of the Federation of Clinical Immunological Societies (FOCIS), Paris, France. Invited speaker.
- 20 May, 2003 American Society for Microbiology Annual Meeting, Washington, DC. Invited symposium speaker.

- 1-2 June, 2003 Nobel Forum on Vaccines and Immunotherapy, Stockholm, Sweden. Invited plenary speaker.
- 29 Sept.-3 Oct., 2003 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited plenary session speaker, special lecture.
- 14-17 Oct., 2003 MD Anderson 56th Annual Symposium on Fundamental Cancer Research: Cancer Immunity: Challenges for the Next Decade, Houston, TX. Invited plenary speaker.
- 1 Dec., 2003 USDA Agricultural Research Service National Immunology Conference, Bethesda, MD. Invited Keynote Speaker.

2004

- 6-11 Jan., 2004 Keystone Symposium on Rational Design of Vaccines and Immunotherapeutics, Keystone, CO. Invited plenary speaker.
- 25-30 Mar, 2004 Keystone Symposium on Immune Evasion, Taos, NM. Invited plenary speaker.
- 17-21 Apr, 2004 American Association of Immunologists Annual Meeting, Washington, DC. Invited Symposium Chairperson and Speaker.
- 29-30 Apr, 2004 10th WRAIR National Symposium on Basic Aspects of Vaccines, Bethesda, MD. Invited Symposium Chairperson and Speaker.
- 13-15 June, 2004 International Workshop on Cancer Vaccines, Siena, Italy. Invited plenary speaker.
- 15-18 June, 2004 International Colloquium on Innate and Adaptive Immunity after Transcutaneous or Mucosal Vaccination, Veyrier du Lac, France. Invited plenary speaker.
- 18-24 July, 2004 12th International Congress of Immunology and 4th Annual Conference of the Federation of Clinical Immunological Societies, Montreal, Canada. Invited minisymposium speaker.
- 6 Sept., 2004 Queensland Institute of Medical Research, Brisbane, Australia. Invited seminar speaker.
- 8-13 Sept, 2004 3rd International Workshop on NKT Cells and CD1-mediated Antigen Presentation, Heron Island, Australia. Invited plenary speaker.

- 10-13 Oct, 2004 International Symposium on Tumor Escape and Its Determinants, Salzburg, Austria. Invited plenary speaker.
- 31 Oct-4 Nov, 2004 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited Symposium Chairperson and Speaker.
- 17 Nov, 2004 The 2004 Tadeusz J. Wiktor Memorial Lecture, Wistar Institute, University of Pennsylvania, Philadelphia, PA.

2005

- 19-24 March, 2005 Keystone Symposium on Basic Aspects of Tumor Immunology, Keystone, CO. Invited Speaker and workshop chair.
- 29 Aug-2 Sept, 2005 International Meeting of the Institute of Human Virology, Baltimore, MD. Invited Symposium Chairperson and Featured Speaker
- 19-21 Sept, 2005 NIH Immunology Interest Group Retreat, Airlie, VA. Invited session chair and organizer.
- 22-23 Sept, 2005 International NCI Symposium on Translational Immunology Related to Cancer, Bethesda, MD. Organizer, Session Chair, and Plenary Speaker.
- 24 Oct., 2005 Albert Einstein College of Medicine, Bronx, NY. Invited seminar speaker.
- 10-11 Nov, 2005 CHAVI Conference on Mucosal Immunity and Vaccines, Duke University, Durham, NC. Invited plenary speaker.
- 16-19 Nov, 2005 First International Dead Sea Conclave on HIV and Cancer Vaccines, Dead Sea, Jordan Valley Marriott Resort and Conference Center, Jordan. Invited session chair and plenary speaker.
- 13-14 Dec, 2005 Boston University International Conference on Biodefense, Boston, MA. Invited plenary speaker.
- 16 Dec, 2005 Laboratory of Experimental Immunology, Frederick Cancer Research and Development Center, CCR, NCI. Invited seminar speaker.

2006

- 5-7 Feb, 2006 Hasumi Foundation International Symposium on Cancer Vaccines, Bethesda, MD. Invited Plenary Speaker.

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| 9 Feb, 2006 | NCI Symposium on Inflammation and Colon Cancer, Bethesda, MD. Invited panel discussant. |
| 5-9 March, 2006 | American Association for Asthma, Allergy, and Immunology Annual Meeting, Miami Beach, FL. Invited Plenary Speaker. |
| 26-29 May, 2006 | International Symposium on Cancer Vaccines, Naples, Italy. Invited Plenary Speaker. |